REMARKS

This Amendment is responsive to the Office Action of February 8, 2006. A request for extension of time and the appropriate fee are included.

Pending Claims

Claims 1-27 were pending prior to the issuance of the Office Action, with Claims 8, 9, 11, 12 and 25-27 withdrawn from consideration pursuant to Applicant's 10/7/05 response to the Office's restriction requirement. Applicant gratefully acknowledges the Examiner's indication of allowable subject matter in Claims 15 and 18-21.

Applicant has amended Claims 1, 13, and 22, and has also cancelled Claim 14 in light of having incorporated it into Claim 13. As such, Claims 1-7, 10 and 13-24 are now pending. Applicant respectfully submits that all of the pending claims are allowable based on the above claim amendments and following remarks.

Toy – 102(b) - Claims 1-4, 6, 7, 10, 13 and 14

The Office Action rejects Claims 1-4, 6, 7, 10, 13 and 14 under 35 U.S.C. 102(b) as anticipated by Toy. Claim 14 has been canceled in light of its incorporation into Claim 13. Claims 1 and 13 are the independent claims in this group of claims. Applicant respectfully traverses based on the above amendments to independent Claims 1 and 13 and the following comments.

Amended Claims 1 and 13 require, among other things, a needle assembly having bifurcated portions and, of particular significance to Toy, "***a sharp***

distal tip of the needle assembly being integral with at least one of the bifurcated portions". Applicant's Figure 13 illustrates one embodiment of the claimed invention where, as emphasized here with a large arrow, the sharp distal tip 22b is integral with bifurcated portion 36b:

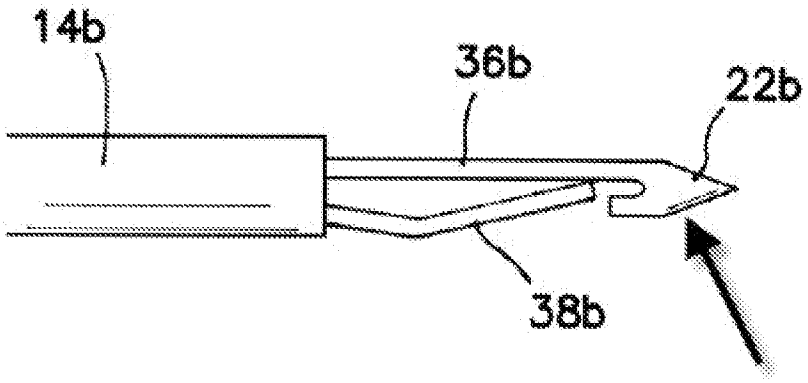


FIG. 13

By contrast, and as best shown in Figure 1 from Toy (large arrows added), Toy does not teach or suggest the claimed structure in that Toy discloses a suture passer 1 with a large pointed head 6 that is <u>not</u> integral with the needle shaft 3, but rather is provided separately and somehow joined to the needle shaft 3:

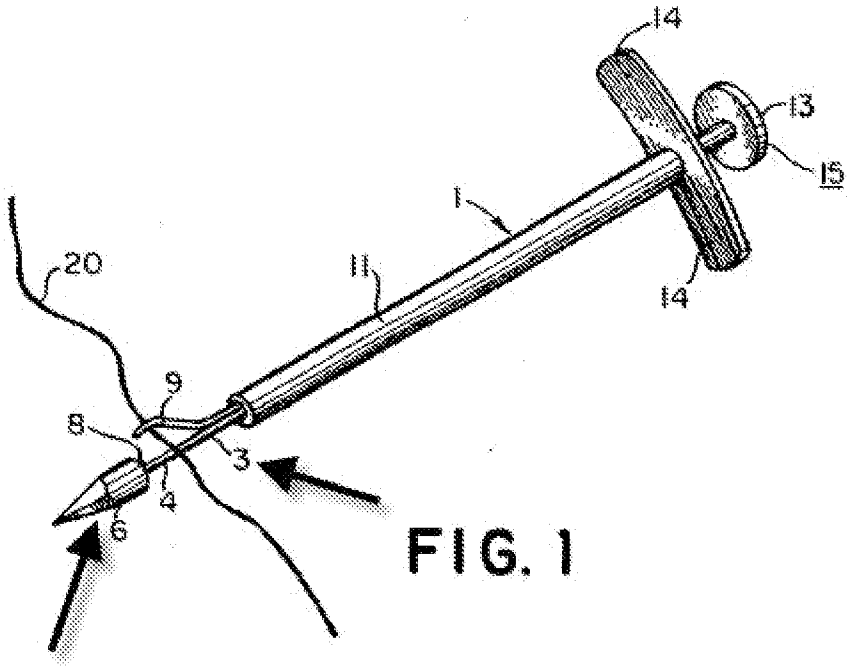


FIG. 1

Based on the foregoing, Applicant respectfully submits that Claims 1-4, 6, 7, 10, and 13 are not anticipated by Toy.

Skiba – 102(e) - Claims 1, 2, 13, 14, 16, 17 and 22

The Office Action rejects Claims 1, 2, 13, 14, 16, 17 and 22 under 35 U.S.C. 102(e) as anticipated by Skiba. Claim 14 has been canceled in light of its incorporation into Claim 13. Claims 1, 13 and 22 are the independent claims in this group of claims. Applicant respectfully traverses based on the above amendments to independent Claims 1, 13 and 22, and the following comments.

Amended Claim 1 requires the following element which, as explained below, is neither taught nor suggested by Skiba:

> a needle assembly disposed at the distal end of the actuating rod and movable back and forth with the actuating rod between an extended state relative to the elongate shaft and a retracted state relative to the elongate shaft;
>
> bifurcated portions of the needle assembly defining a suture slot, the bifurcated portions having a proximate relationship when the needle assembly is in the retracted state and having a separated relationship when the needle assembly is in the extended state;

Amended Claim 13 similarly requires:

> a needle assembly having a needle movable in a needle housing between a free suture state, a captured suture state, and a locked suture state;
>
> bifurcated portions of the needle assembly defining a suture slot, the bifurcated portions having a proximate relationship when the needle assembly is in the captured suture state and having a separated relationship when the needle assembly is in the free suture state;

And, amended Claim 22 requires:

> providing a suture device including a hollow shaft with a proximal end and a distal end, an actuating rod disposed in the shaft, and a needle assembly carried within the hollow shaft and moveable by the rod between a deployed position relative to the hollow shaft and a retracted position relative to the hollow shaft;

Applicant's Figure 11 and 13 illustrates one embodiment of the claimed invention where a needle assembly is moveable relative to a hollow shaft 14b, and where bifurcated portions 36b, 38b have a separated relationship in Figure 11, and a proximate relationship in Figure 13:

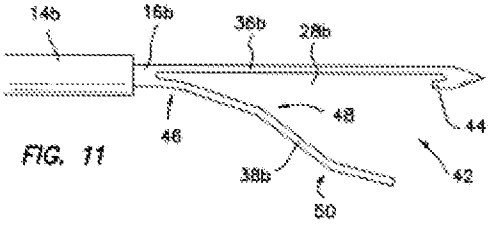


FIG. 11

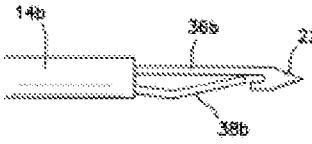


FIG. 13

Skiba discloses a suturing apparatus 1800 having a sharpened tip 1808, as shown by the following reproduction of Skiba's Figure 18:

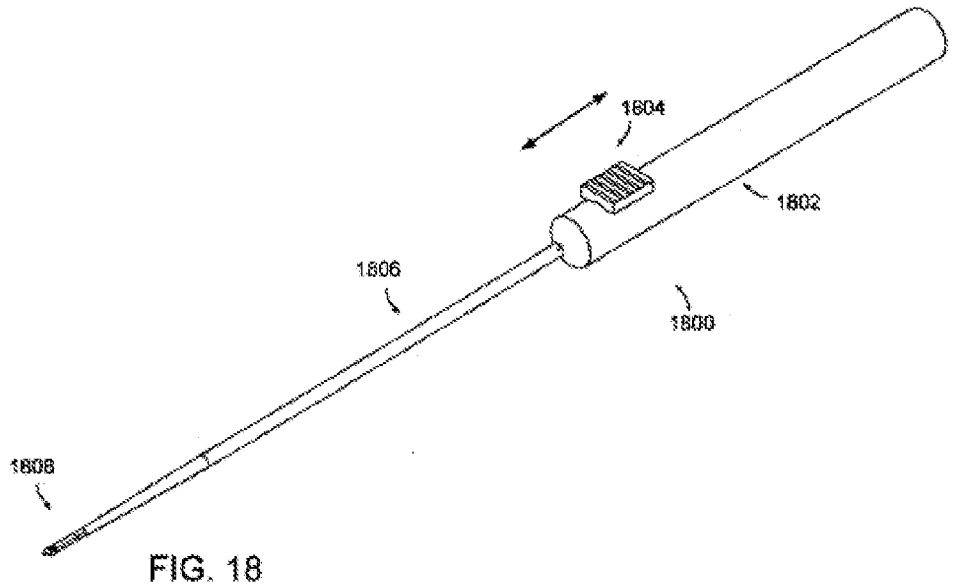


FIG. 18

However, Skiba's Figures 20 and 21 do not disclose a surgical device that is structured as claimed. In Skiba, only the "locking element" is moveable. The needle 1808 itself is not moveable, and the needle does not have bifurcated portions that change position relative to one another. This is made clear from Skiba's written disclosure and related drawings. In particular, Skiba notes that Figure 19 is a close-up of a sharpened tip 1808 having an opening 1902 and "locking element" 1904:

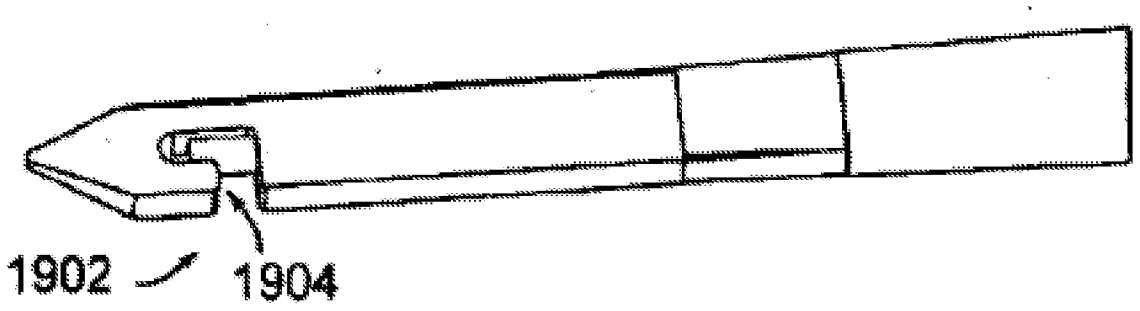


FIG. 19

Skiba further notes that the locking element 1904 works as follows (see col. 4, lines 61-67):

> FIG. **20** further illustrates the use of the locking mechanism … FIG. **20** shows a schematic view of the sharpened tip **1808** with opening **1902**. Sharpened tip **1808** has side-loading capability and locking element **1904**, which can be selectively placed in any of the foregoing positions by movement of the locking element in the direction of arrow **2002**.

Then, taking a closer look at Figures 20 and 21 which show a needle embodiment with side loading capability and a needle with a through hole, one sees how the locking element 1904 moves back and forth between an open and closed position as suggested by arrow 2002 (the needle in Figure 20 has been cross-hatched in these remarks to emphasize the separate locking element):

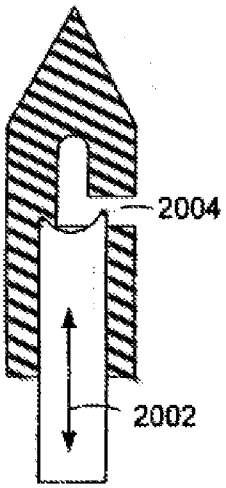


FIG. 20

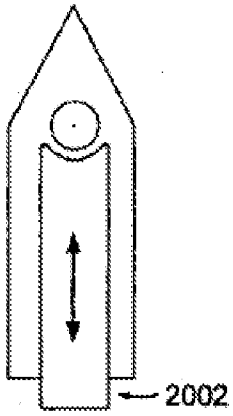


FIG. 21

Note that the cross-hatched needle does not move relative to an elongate shaft having a hollow configuration as required by the Claims.

Note also that even if the cross-hatched needle is interpreted to have bifurcated portions, those portions are always fixed relative to one another, and they do

not have a proximate relationship when the needle is retracted and a separated relationship when the needle is extended.

Based on the foregoing, Applicant respectfully submits that Claims 1, 2, 13, 16, 17 and 22 are not anticipated by Skiba.

Chu – 102(e) - Claims 1- 4, 6 and 7

The Office Action rejects Claims 1-4, 6 and 7 under 35 U.S.C. 102(e) as anticipated by Chu. Claim 1 is the only independent claim in this group of claims. Applicant respectfully traverses based on the above amendments to independent Claim 1.

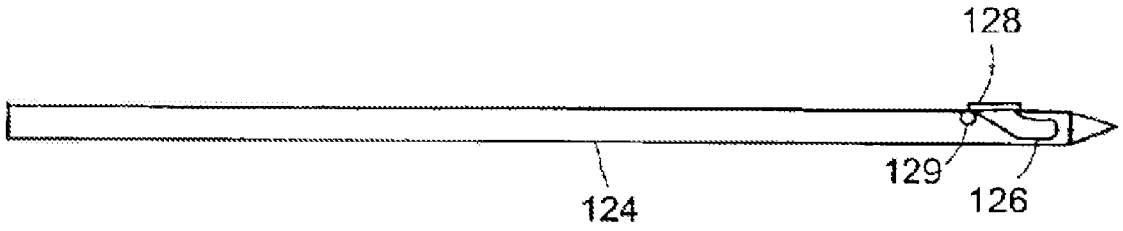
Claim 1 includes the following claim elements:

> bifurcated portions of the needle assembly defining a suture slot, the bifurcated portions having a proximate relationship when the needle assembly is in the retracted state and having a separated relationship when the needle assembly is in the extended state;
>
> ***
>
> the bifurcated portions being biased to the separated relationship.

Chu discloses an apparatus for placing sutures that includes a needle with bifurcated portions. However, those portions are not moveable relative to one another between a proximate relationship and a separated relationship, and are also, therefore, not biased to the separated relationship.

In more detail, Chu discloses an apparatus that uses a needle 124 shaped like a crochet hook and it has a hook shaped distal portion 126 and a flap or "latch" 128

that opens and closes a side notch (this simplified figure of the "crochet hook" needle was excerpted from Chu's Figure 2H):



Note that the needle 124 arguably has bifurcated portions defining a suture slot. However, the needle's bifurcated portions do not change their position relationship relative to one another. They remain fixed relative to one another and it is the flap 128 that opens and close the entry to the needle's suture slot.

Based on the foregoing, Applicant respectfully submits that Claims 1-4, 6 and 7 are not anticipated by Chu.

Diduch – 102(e) - Claims 13, 14, and 22-24

The Office Action rejects Claims 13, 14, and 22-24 under 35 U.S.C. 102(e) as anticipated by the published patent application to Diduch. Claim 14 has been canceled in light of its incorporation into Claim 13. Claims 13 and 22 are the independent claims in this group of claims. Applicant respectfully traverses based on the above amendments to independent Claim 13 and 22.

Claim 13 now includes several additional elements, including the requirements of Claim 14, i.e. that the needle is movable between a free suture state, a captured suture state, and a locked suture state. Diduch, however, does not disclose a free suture state in that the suture is always enclosed if the needle is used.

Claim 13 has also been amended to clarify the bifurcating step as follows (emphasis showing changes):

> bifurcating the needle to form at least one pair of arms defining a suture slot, with at least one arm being separated from the others at one of a distal end or a proximal end to permit suture to enter the suture slot, the arms being movable between a proximate position associated with a first slot size and a spaced position associated with a second slot size greater than the first slot size;

Diduch, by contrast, does not teach or suggest this step.

Based on the foregoing, Applicant respectfully submits that Claims 13 and 22-24 are not anticipated by Diduch.

Withdrawn Claims

In light of the fact that the withdrawn Claims 8, 9, 11, 12 and 25-27 all depend from allowable claims, Applicant respectfully requests that the withdrawn claims be passed to issue as well.

Summary

It now appearing that this case is fully in condition for allowance as to Claims 1-7, 10 and 13-24, and also as to previously withdrawn Claims 8, 9, 11, 12 and 25-27 , Applicants earnestly solicit a notice to that effect. Applicants invite the Examiner to call the undersigned attorney if it appears that a phone conference would further this case in any way.

Respectfully submitted,

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